EXHIBIT 2

T0055/10-3302
European Patent No. 1 264 597
in the name of The Children's
Medical Center Corporation

DECLARATION OF RYUZO OHNO, M.D.

I, Ryuzo Ohno, a President Emeritus of Aichi Cancer Center, Nagoya, Japan, do declare and state that:

1. A copy of my CV is attached as Exhibit 1 to this declaration, which gives full details of my career to date. As will be evident, I have been a cancer specialist for 44 years.

2. I have been retained, by the exclusive licensee of EP 1,264,597, Celgene Corporation, as an expert and consultant in connection with this patent. I also serve on the scientific advisory board of the Japanese subsidiary of Celgene Corporation K.K.

3. I have read and am fully familiar with the invention described in EP 1,264,597. I understand that it relates to the use of thalidomide in the treatment of various oncogenic diseases, and in particular, the treatment of solid and blood-borne tumours *per se*.

4. I have also read and am fully familiar with the paper cited in the opposition proceedings of EP 1,264,597, i.e. Olsen *et al.*, Clinical Pharmacology and Therapeutics, 1965, Vol. 6, No.3, pp. 292-297 (D1).

5. When oncologists give anti-tumor drugs to patients, many of which have some kind of adverse side effects, we usually aim to achieve at least objective effects, i.e. shrinkage of tumor size, and hopefully cure the disease or at least try to prolong patients' survival. The term "objective

improvement" means that there is some shrinkage of tumor size, which can be determined by its direct measurement, or by images of X-ray, CT or radio-isotope scintigram.

6. In contrast to "objective improvement", to an oncologist, the terms "subjective improvement" or "subjective benefit" mean that the patients themselves think that there is some improvement in their well-being irrespective of the existence of objective improvement or not. Subjective improvement means that patients feel better in some way, i.e. palliation.

7. I have reviewed D1, which was published in 1965, and which reported that thalidomide was administered to 21 patients with 14 tumor types for 1 week to 34 weeks. D1 does not disclose or provide any evidence of a therapeutic effect of thalidomide against any of these 21 tumors. Rather, from the point of an oncologist, it actually teaches that thalidomide was not effective in any tumor tested.

8. As an oncologist, I do not think that D1 presents that thalidomide brought about any "objective" improvement. On the contrary, D1 states, in its Summary, "without objective evidence of tumor regression". It merely refers to "subjective" improvement. Thus, in my opinion, D1 does not show thalidomide to be an anti-tumor agent.

9. I have carefully considered the data provided in D1 for patients 13 and 17, and deduced from these data, that both patients only showed subjective improvement. Since thalidomide was introduced into clinics as an anti-emetic or sleeping pill with sedative-hypnotic activity, it is quite plausible that these 2 patients might have felt better if they had had some kind of nausea, anxiety or sleeping problems caused by their cancer. Therefore, it is no surprise that they showed signs of subjective improvement while receiving thalidomide.

10. I have considered the data included in EP 1,264,597, and note that the inventor used the well-known model for studying angiogenesis, i.e. inhibition of bFGF-induced angiogenesis in rabbit corneas. I believe that the data provided in EP 1,264,597 clearly show that thalidomide is able to inhibit angiogenesis. Since angiogenesis is now known to be critical for tumor growth, in my opinion, thalidomide could be used to treat tumours.

11. The Opposition Division has said that *in vivo* measurement of tumour growth or regression at the time D1 was published (1965) may not have been possible or straightforward. However, I do not agree. Even in 1965, a number of reliable methods were already available for measuring the response in cancer patients to treatment, including direct measurement of tumor size, regular X-ray, X-ray Tomography, and, in the case of multiple myeloma, measurement of immunoglobulins (gamma-globulin) and examination of bone marrow.

12. If tumors (or their radiological images) completely disappeared by the action of an anti-tumor drug, it is defined as complete response (CR). If they partially shrink more than 50%, it is defined as a partial response (PR). If they shrink between 25 to 50%, it may be called a minor response (MR). If they shrink, but less than 25% or enlarge but no more than 25%, it is defined as a stable disease (SD). If they enlarge more than 25%, it is defined as a progressive disease (PD). CR and PR but not MR are regarded as meaningful responses. Therefore, even in 1965, oncologists would have been able to provide a scientific assessment of the efficacy of thalidomide on tumour growth.

13. D1 is a paper from the Eastern Cooperative Oncology Group (ECOG), a well-established and reliable cooperative group, and the study was financially supported by National Cancer Institute (NCI) of USA. Therefore, if thalidomide was considered to have had any hint of promise as an anti-tumor drug, further studies would have doubtlessly been

attempted in the Eastern Cooperative Oncology Group as well as in other parts of the USA.

14. It was possible that some oncologists could have found a hint of promise by reading D1 and tried thalidomide for cancer patients. However, if thalidomide treatment had resulted in some form of objective response, they would have certainly reported their findings in medical journals. However, to the best of my knowledge, there was no such paper for almost 30 years since 1965.

15. Cancer is basically a disease of the elderly. Therefore, most cancer patients are not at a child-bearing age. Besides, since, in the 1960s, advanced cancer killed patients within a few years, it was out of the question that oncologists or even patients themselves would have ever avoided effective anti-cancer drugs simply because they may have had a teratogenic effect. An amazingly effective drug, which is teratogenic, is all-trans retinoic acid (ATRA), which is presently the first choice drug against acute promyelocytic leukemia (APL). It cures more than 80% of patients with APL, and is even administered to female APL patients of child-bearing age because of its effectiveness. Patients are advised not to get pregnant, but if it should happen, abortion is forced.

16. In summary, I was a post-doctoral clinical fellow at M.D. Anderson Hospital and Cancer Institute (presently, M.D. Anderson Cancer Center), which is one of the best cancer hospitals in the world, from 1967 to 1969. Even at that time, if I had read D1, I would not have thought that thalidomide was a promising anti-tumor drug. As a matter of fact, there was never any mention of thalidomide at M.D. Anderson Cancer Center during my 2-year stay. As I already stated, D1 is a paper from the Eastern Cooperative Oncology Group (ECOG), and the study was supported by NCI. If thalidomide had been considered to have any hint of promise as an anti-tumor drug, further studies would definitely have been attempted in ECOG as well as in other parts of the world including M.D. Anderson

Cancer Center. Since oncologists were desperately searching for new promising anti-tumor drugs at that time, they would certainly have tested thalidomide, and NCI would have also encouraged them to conduct further clinical studies, if they had thought that D1 gave even a slight impression of being a promising anti-tumor drug.

17. I hereby declare that all statements made herein of my own knowledge are true.

Declarant:.....

RYUZO OHNO, M.D

Date: March 22, 2010

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